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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,550	02/27/2002	Kazuhito Rokutan	ASAM.0051	5577

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EXAMINER

DEJONG, ERIC S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/083,550

Applicant(s)

ROKUTAN ET AL.

Examiner

Eric S. DeJong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-11 is/are pending in the application.
- 4a) Of the above claim(s) 2-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1 sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 June 2005 has been entered.

Withdrawal of Claim Objection

The previous objection of claim 11 has been withdrawn in view of amendments made to the instant claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Lipshutz et al. in light of Smith et al.

The instant claim is drawn to an oligonucleotide array comprising an array of multiple oligonucleotides with different base sequences fixed onto known and separate

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positions on a support substrate. Said oligonucleotides are biological stress related genes or complementary sequences of said genes and multiple oligonucleotides are classified according to their gene functions wherein the support substrate has fixation regions divided according to said classification.

[Claim 11]: Lipshutz et al. sets forth the synthesis and construction of whole genome oligonucleotide arrays with extremely high information content containing oligonucleotide sequences derived from or complimentary to genes from the human genome. See Lipshutz et al., abstract. Figure 2 of Lipshutz et al. provides a display of an oligonucleotide array from gene expression monitoring containing approximately 40,000 human genes and ESTs representative of the human genome. See also Lipshutz et al., page 21, column 1, line 13 through page 22, column 2, line 29. Each set probe (containing only 4 probes per gene or EST) occupies a distinct and separate 22x22 μ M region in the 1.28x1.28 cm array. The separated arrangement of probes on the array allows for specific monitoring of selectable genes and serves as a sensitive, unique, and sequence specific detector. See especially Lipshutz et al., page 21, column 1, line 13 through column 2, line 16. The segregation of oligonucleotide probe sets correlating to a single gene or EST region within the human genome anticipates the claimed limitation fixing oligonucleotides onto known and separate positions on a support substrate and further classifying each oligonucleotide according to the corresponding gene function, wherein genes are classified in accordance to (1) internal and external standards genes for proof reading (broadly construed as housekeeping genes, see the instant specification page 7, line 21 through page 8, line 18), (2) stress-

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related genes related to heat shock protein and hormone genes that decreases under stress, (3) cytokine genes, (4) genes that induce cell death, (5) genes related to anti-inflammation and wound healing and genes related to cell growth inhibition, (6) transcription factor and signaling molecules related to immune response, (7) induction of cytokine, (8) transcription factor and signaling molecules related growth inhibition, and (9) transcription factor and signaling molecules. Smith et al., relied upon as a supporting document, discloses known genes within the human genome that are related (classified) to the above described functions. See for example, Smith et al., Tables 5 and 10, Examples 5, 12, and 17 and column 33, line 31 through column 34, line 60. Therefore, the oligonucleotide array disclosed by lipshutz et al. containing approximately 40,000 identifiable, separate, and distinct probes sets representative of the human genome inherently contains the instantly claimed classified, multiple oligonucleotides that are fixed onto known and separate positions on a support substrate.

Conclusion

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight

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(EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center at (800) 786-9199.

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John S. Brusca 26 July 2005

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER